REQUEST TO DEVIATE FROM A NAHLN TESTING SOP INSTRUCTION GUIDE

NAHLN Laboratories must submit a completed Request to Deviate from a NAHLN Testing SOP form prior to off protocol use of NAHLN assays. To submit a form, the NAHLN Laboratory needs to complete blocks A through E. This instruction guide will provide information on how to complete the form, how to submit the form, and how the decision on the request will be reported back to the submitting NAHLN Laboratory.

Completing the form

Block A: Contact information for the laboratory and the Laboratory Director including:

- Name of requesting laboratory
- Laboratory Director's name
- Laboratory Director's phone number
- Laboratory Director's e-mail address

Block B:

- Enter the date range or time period for when the deviation is requested. It is acceptable to list "indefinite" as a response.
- Enter the associated NAHLN SOP number
- Enter the associated NAHLN SOP name

Block C:

• Enter the description of the proposed planned deviation including specific information.

Block D: Technical justification

• Enter a technical justification for the proposed planned deviation. Provide an explanation of the verification process used to determine that the deviation will not affect test results.

Block E:

Laboratory Director's signature and date

Submitting the form to the NAHLN Program Office

- Notify the NAHLN Program Office at 515-337-7731 that a request to deviate from a NAHLN testing SOP is being either faxed or e-mailed for approval.
- Fax form with block A-E completed to 515-337-7397 or scan and e-mail to barbara.m.martin@aphis.usda.gov **AND** nahln@aphis.usda.gov.

• Use the following for the subject line of the e-mail submission or on the fax cover sheet: Request immediate review: Submitting a "Request to Deviate from a NAHLN Testing SOP"

Reporting of approval or rejection to the submitting NAHLN Laboratory (Block F)

- The submitted request will be reviewed and signed by the NAHLN Coordinator and the NVSL Reference Laboratory.
- The submitted request will either be checked as "deviation approved" or "deviation rejected". NVSL Officials must concur in order for deviation to be accepted.
- The reviewed form will be returned to the submitting laboratory by e-mail.
- If the deviation is rejected, the e-mail will include the reason for the rejection.